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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,705	11/21/2001	Judith K. Gwathmey	JGT-004	3899

959 7590 01/14/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,705

Applicant(s)

Gwathmey et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 21, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,5,6 6) ☐ Other:

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DETAILED ACTION

Claims 1-26 are pending and subject to restriction requirement

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a method of isolating cells by treating the tissue samples with a solution of decreasing CaCl_2 concentrations and after enzymatic dissociation with a solution of increasing CaCl_2 concentrations, classified in class 435, subclass 378, for example.
- II. Claims 14-17, drawn to a cell culture medium and method of culturing cells in the culture medium, classified in class 435, subclass 383, for example.
- III. Claims 18-24, drawn to a method of isolating cells by treating the tissues with a solution of a constant CaCl_2 concentration and digestive enzymes, classified in class 435, subclass 381, for example
- IV. Claims 25 and 26, drawn to a method for isolating myocardial cells by treating the tissues with a solution of a constant CaCl_2 concentration and after enzymatic dissociation with a solution of increasing CaCl_2 concentrations, classified in class 435, subclass 325, for example.

The inventions are distinct, each from the other because of the following reasons:

The instant application contains claims directed to several distinct methods for isolating cells comprising different steps of applying to the tissue and/or to suspended cells several various

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compositions with different CaCl_2 concentrations before, during and after enzymatic digestion in order to isolate cells and in order to culture the isolated cells as claimed.

The Group I method of isolating cells is different from the Group III and IV methods of isolating cells because it requires the use of decreasing concentrations of CaCl_2 before enzymatic digestion of tissue as claimed what is not required in the methods of Groups III and IV, drawn to the use of constant CaCl_2 concentrations before or during enzymatic digestion.

The Group II cell culture medium composition and method of culturing cells are different from the Group I composition/method because the Group II invention requires the use of one constant concentration of CaCl_2 for culturing suspended cells as claimed but the compositions in the method of Group I requires the use of changing concentrations of CaCl_2 in various culture media.

The Group III cell culture medium composition and method require the use of nitrilotriacetic acid what is not required for the Group II composition and method as claimed.

The Group IV cell culture medium composition and method require the use of Tyrode's solution what is not required for the Group II composition and method as claimed.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or make

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obvious the any of the other groups. For these reasons restriction for examination purposes is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

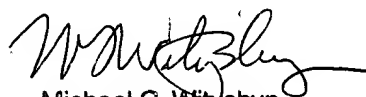
Vera Afremova

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January 2, 2003.

VERA AFREMOVA

PATENT EXAMINER


Michael G. Wityshyn
Supervisory Patent Examiner
Technology Center 1600